

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for seven approved new animal drug applications (NADAs) for clopidol Type A medicated articles and combination drug medicated chicken and turkey feeds from Aventis Animal Nutrition, Inc., to Merial Ltd.

DATES: This rule is effective [*insert date of publication in the **Federal Register***].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Aventis Animal Nutrition, Inc., 3480 Preston Ridge Rd., suite 650, Alpharetta, GA 30005-8891, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 34-393, 40-264, 41-541, 44-016, 46-209, 49-934, and 99-150 for clopidol Type A medicated articles and certain combination clearances for use in medicated feeds for chickens and turkeys to Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640. Accordingly, the agency is amending the regulations in § 558.175 (21 CFR 558.175) to reflect the transfer of ownership. Section 558.175 is also being changed to a table format.

Following the change of sponsor of these NADAs, Aventis Animal Nutrition, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is being amended to remove the entries for this sponsor.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by

removing the entry for “Aventis Animal Nutrition, Inc.” and in the table in paragraph (c)(2) by removing the entry for “011526”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

4. Section 558.175 is revised to read as follows:

§ 558.175 Clopidol.

(a) *Specifications.* Type A medicated article containing 25 percent clopidol.

(b) *Approvals.* See No. 050604 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used as follows:

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) 113.5		Broiler chickens and re-place ment chickens intended for use as caged layers: As an aid in the prevention of coc- cidiosis caused by <i>E. tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Do not feed to chickens over 16 weeks of age.	050604
(2) 113.5	Bacitracin methylene disalicylate 4 to 50	Broiler chickens: As in paragraph (d)(1) of this section; for in- creased rate of weight gain.	Feed continuously as the sole ration from the time chicks are placed in floor pens until slaughter. Do not feed to chickens over 16 weeks of age; bacitracin methylene di- salicylate as provided by No. 046573 in § 510.600(c) of this chapter.	050604
(3) 113.5	Bacitracin 4 to 25 plus roxarsone 45.4	Broiler chickens: As in paragraph (d)(1) of this section; for growth promotion, feed effi- ciency; improved pigmentation, and increased rate of weight gain.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicy- late or bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter.	046573 050604
(4) 113.5	Bacitracin zinc 5 to 25	Broiler chickens: As in paragraph (d)(1) of this section; for in- creased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; bacitracin zinc as provided by No. 046573 in § 510.600(c) of this chapter.	046573 050604
(5) 113.5	Chlortetracycline 100 to 200	Broiler and replacement chick- ens: As in paragraph (d)(1) of this section; for control of in- fectious synovitis caused by <i>Mycoplasma synoviae</i> suscep- tible to chlortetracycline.	Feed continuously as sole ration from the time chicks are placed in floor pens for 7 to 14 days.	050604
(6) 113.5	Lincomycin 2 to 4	Broiler chickens: As in paragraph (d)(1) of this section; for in- creased rate of weight gain and improved feed efficiency.	Do not feed to chickens over 16 weeks of age; as lincomycin hydrochloride monohydrate.	000009

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Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(7) 113.5	Roxarsone 45.4	Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section; for growth promotion, feed efficiency; and improved pigmentation.	Do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.	050604
(8) 227		Broiler and replacement chickens intended for use as caged layers: As in paragraph (d)(1) of this section.	Feed continuously as the sole ration; feed up to 16 weeks of age if intended for use as caged layers; withdraw 5 days before slaughter if given at the level of 0.025 percent in feed or reduce level to 0.0125 percent 5 days before slaughter.	050604
(9) 113.5 or 227		Turkeys: As an aid in the prevention of leucocytozoonosis caused by <i>Leucocytozoon smithi</i> .	For turkeys grown for meat purposes only; feed continuously as the sole ration at 0.0125 or 0.025 percent clopidol depending on management practices, degree of exposure, and amount of feed eaten; withdraw 5 days before slaughter.	050604

Dated: March 25, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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